PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: ROBERT F. FRIJOUF
FRIJOUF, RUST & PYLE, P.A.
201 EAST DAVIS BOULEVARD
TAMPA, FLORIDA 33606

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing *(day/month/year)*	27 OCT 1999 11-22-99
Applicant's or agent's file reference: NONE	REPLY DUE within ONE months from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US98/21604	09 OCTOBER 1998	10 OCTOBER 1997

International Patent Classification (IPC) or both national classification and IPC
Please See Supplemental Sheet.

Applicant
NVID INTERNATIONAL, INC.

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I [X] Basis of the opinion
- II [ ] Priority
- III [ ] Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV [X] Lack of unity of invention
- V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI [ ] Certain documents cited
- VII [ ] Certain defects in the international application
- VIII [X] Certain observations on the international application

RECEIVED
OCT 30 1999
Frijouf, Rust & Pyle, P.A.

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension., see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 10 FEBRUARY 2000.

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	JOHN PAK
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1235

Form PCT/IPEA/408 (cover sheet) (January 1994)*

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VII	[ ]	Certain defects in the international application
VIII	[X]	Certain observations on the international application

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Authorized officer
JOHN PAK

Telephone No. (703) 308-1235

WRITTEN OPINION

International application No.
PCT/US98/21604

I. Basis of the opinion

1. This opinion has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

[X] the international application as originally filed.

[X] the description, pages 1-22 , as originally filed.
pages NONE , filed with the demand.
pages NONE , filed with the letter of _____.

[X] the claims, Nos. 1-35 , as originally filed.
Nos. NONE , as amended under Article 19.
Nos. NONE , filed with the demand.
Nos. NONE , filed with the letter of _____.

[X] the drawings, sheets/~~fig~~ 1-8 , as originally filed.
sheets/~~fig~~ NONE , filed with the demand.
sheets/~~fig~~ NONE , filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

3. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:
NONE

WRITTEN OPINION

International application No.
PCT/US98/21604

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1 not to invite the applicant to restrict or pay additional fees:

Please See Supplemental Sheet.

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

- ☒ all parts.
- ☐ the parts relating to claims Nos. _.

WRITTEN OPINION

Intemational application No.
PCT/US98/21604

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	9, 11-20, 26-29	YES
	Claims	1-8, 10, 21-25, 30-35	NO
Inventive Step (IS)	Claims	26-29	YES
	Claims	1-25 and 30-35	NO
Industrial Applicability (IA)	Claims	1-35	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 9, 11-20 and 26-29 meet the criteria set forth in PCT Article 33(2) because no single prior art can be found that expressly discloses (i) silver citrate formed from 0.05-0.1% by volume silver electrolytically generated in a solution of 5-10% by volume citric acid, (ii) silver citrate from electrolytically generated silver with alcohol and optionally anionic detergent, and (iii) method of making a disinfectant by applying a potential difference to a positive silver electrode and a negative electrode to generate a flow of silver ions in 5-10% by volume of citric acid in water.

Claims 26-29 meet the criteria set forth in PCT Article 33(3) because the prior art does not disclose or suggest the process of making an aqueous disinfectant by electrolytically generating silver ions in 5-10 percent by volume aqueous citric acid solution, as claimed.

Claims 1-35 meet the criteria set forth in PCT Article 33(4) because the claimed invention finds industrial applicability in the disinfection of various substrates.

Claims 1-8, 10 and 30 lack novelty under PCT Article 33(2) as being anticipated by Srivastava et al.

Srivastava et al. expressly disclose 0.5% silver citrate aqueous solution. The aqueous solution must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. See page 209 and Tables 1 and 3 at pages 211-212. While Srivastava's composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. Therefore, instant claims are deemed anticipated.

Claims 1-8 and 10 lack novelty under PCT Article 33(2) as being anticipated by Tsimbler et al. (Chemical Abstracts 87:74283n).

(Continued on Supplemental Sheet.)

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 4, 5, 24, 25, 26, 34 and 35 are objected to under PCT Article 6 as being indefinite.

(1) All of the above noted claims recite citric acid as $C_6H_8O_7$ - H_2O. However, this formula is not necessarily and strictly limited to citric acid. It could be another compound that has the same formula. If a formula is to be used, it must be more specific with respect to bond linkage, etc. to ensure that the correct compound is represented.

(2) Claims 4, 24 and 34 recites $(Ag(CA)_x)+$, but the value for the subscript x is not defined.

(3) Claim 26 recites "**creating** a solution ..." (emphasis added). The emphasized term makes the claim indefinite as "creating" a solution is different from, for example, "providing." Amendment of said term to "providing" or other acceptable alternative terms is suggested.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(6): A01N 37/04, 55/02, 59/00; A61K 31/19, 31/28, 33/38 and US Cl.: 424/618, 619; 422/22, 28; 514/495, 574, 724

IV. LACK OF UNITY OF INVENTION:

2. Although this IPEA did not invite applicant to restrict or pay additional fees, Unity of Invention is lacking for the following reasons:
This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1.

Group I, claims 1-10, 21-25 and 30-35, drawn to an aqueous disinfectant comprising silver citrate in a solution of citric acid and water and a process of making said disinfectant by using as the silver source electrolytically generated silver.
Group II, claims 11-20, drawn to an aqueous disinfectant comprising silver citrate in a solution of citric acid, water and alcohol such as ethyl alcohol.
Group III, claims 26-29, drawn to a process of making an aqueous disinfectant by (i) providing a solution of 5-10% citric acid in water, (ii) spacing a positive silver electrode relative to a negative electrode for enabling the solution to be located therebetween, and (iii) applying a potential difference to the electrodes to establish a flow of silver ions between the electrodes for silver ions to react with the citric acid to form silver citrate.

The inventions listed as Groups I, II and III do not relate to a single inventive concept under PCT Article 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
Group I and Group II are directed to distinct inventive compositions. It is unclear *a priori* whether the alcohol component in Group II would provide for a materially different complex of silver-citrate-alcohol. Therefore, it is not known at this time whether the composition of Group II is a composition with just one more ingredient than Group I or a materially distinct complex of three components. Thus it cannot be said that a special technical feature is shared by Group I and Group II when the alcohol component may materially alter the complex formed in Group II due to, for example, the availability of another ligand and/or different solubility effect brought on by the alcohol. Special technical feature cannot be found when the ingredients of Group II produce a complex that may be materially distinct from that expected of Group I.

The process of Group III does not share a special technical feature with the process of Group I because the process of Group I is only nominally directed to electrolytic generation of silver, whereas the process of Group III is specific with respect to the spacing of the electrodes, the position of the solution, and result of application of potential difference.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

Chemical Abstracts 87:74283n expressly disclose silver citrate complex in aqueous solution. The aqueous solution must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. While the disclosed composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. Therefore, instant claims are deemed anticipated.

Claims 21-25 and 30-35 lack novelty under PCT Article 33(2) as being anticipated by Yamamoto (Chemical Abstracts 118:156836t).

Chemical Abstracts 118:156836t expressly discloses electrolyzing in an aqueous solution containing citrates (and by necessity citric acid) with a silver cathode at 1.5V (preferably ≥3V). The process of the claims 21-25 and 30-35 are directly readable on the process disclosed by Chemical Abstracts 118:156836t. Chelation and formation of a complex are presumed to

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

take place with the same ionic species in the absence of contrary evidence. The claims are thereby anticipated.

Claims 21-25 and 30-35 lack an inventive step under PCT Article 33(3) as being obvious over Yamamoto (Chemical Abstracts 118:156836t).

Chemical Abstracts 118:156836t expressly discloses electrolyzing in an aqueous solution containing citrates (and by necessity citric acid) with a silver cathode at 1.5V (preferably ≥3V). The process of the claims 21-25 and 30-35 are directly readable on the process disclosed by Chemical Abstracts 118:156836t. Chelation and formation of a complex are presumed to take place with the same ionic species in the absence of contrary evidence. The claims therefore lack an inventive step.

Claims 1-20 and 30 lack an inventive step under PCT Article 33(3) as being obvious over Srivastava et al.

Srivastava et al. expressly disclose 0.5% silver citrate aqueous solution as having "very good antibacterial activity against organisms studied (Table 1)" (see p. 213, column 1, second full paragraph). The aqueous solution must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. See page 209 and Tables 1 and 3 at pages 211-212. While Srivastava's composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. To further add to the antimicrobially active silver citrate another active substance such as alcohol for its own antimicrobial, disinfecting or solvent functionality would have been well within the skill of the routineer in the art. Therefore, the claimed invention as a whole would have been obvious to the routineer in this art; and the instant claims lack unity of invention under PCT Article 33(3).

Claims 1-20 and 30 lack an inventive step under PCT Article 33(3) as being obvious over Maurer et al. (US 4,055,655).

Maurer et al. disclose controlling microbes with a metal complex of heavy metal ion such as silver with a polyfunctional organic ligand such as alph-hydroxy polycarboxylic acid (see e.g. claims 1-3 and 8). Citrates are disclosed (column 4, lines 1-13). The aqueous solution (see e.g. column 13, lines 36-39) must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. While Maurer's composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. To further add to the antimicrobially active silver citrate another active substance such as alcohol for its own antimicrobial, disinfecting or solvent functionality would have been well within the skill of the routineer in the art. Therefore, the claimed invention as a whole would have been obvious to the routineer in this art; and the instant claims lack unity of invention under PCT Article 33(3).

---------- NEW CITATIONS ----------

Chem. abstr., Vol. 118, No. 16, 19 April 1993 (Columbus, OH, USA), page 628, column 2, the abstract No. 118:156836t, YAMAMOTO, M. 'Electrochemical removal of discoloration on silver product surface.' JP 04-297599 A, 21 October 1992.